

Food Allergens and Food Safety: A Global Perspective with Respect to Codex Alimentarius

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Abstract: Over the last two decades, food allergens are being recognized as one of the food hazards. This serious food safety issue is being addressed in different countries not only in terms of their biological and clinical characteristics, but also in terms of various standards of allergen management in food industries. This abnormal immune response caused by food allergens affects the quality of life especially in children and influences their overall health and retards normal growth, along with they suffer from ailments like eating disorders, depression, sometimes even death which is the most adverse impact of food allergy. Every country has their own set of guidelines to deal with the food allergens especially developed countries, food allergen guidelines is not well documented in developing countries. FAO/WHO is providing assistance to developing countries in strengthening their food safety guidelines. The Codex Alimentarius was formulated by the two organizations FAO/WHO in the year 1960; it is a collection of food standards in a integrated, codified style, together with associated material such as codes of hygiene and good manufacturing practices that should be followed by industries during various production stages of a food item. In both developed and developing nations, the Food Chemical Codex or the Codex Alimentarius aims to protect public health and implement fair trade practises for the trading of food items.

Key words: Food allergens, Codex alimentarius, food safety, FAO, WHO

1. Introduction

Food safety and food quality are two important aspect related to food processing, manufacturing or production that needs a lot of attention. Food safety hazards like biological hazards (bacteria, viruses, parasites, protozoan, and prions etc.), chemical hazards like (pesticides, agricultural contamination, heavy metals, natural biological toxins, adulterants etc.), have already gained attention from food safety researchers and regulators both in developed and developing countries [1]. Food allergy is one of the food hazards that are gaining immediate attention in food industries, this is because the number of people, especially children, who are getting susceptible to food allergens and it has become a serious public health problem. Medical science has made tremendous progress but

food allergy seems to be an incurable ailment. Food allergens are showing only increase in their frequency, this can be confirmed by seeing the statistics of peanut allergy which has doubled over the past 5 years [2]. Avoidance of contamination of food stuff with allergens during food production and accurate labelling of such allergic food stuff by the manufacturers is the only option to control severe attacks to these allergic foods among susceptible individuals. Since food allergies are not static in nature, an individual may develop an allergy towards certain food stuff later in life, he/she may outgrow some of the food allergies at some point, for example, milk allergy, or sometimes it can be a lifelong illness, for example, peanut allergy [2].

In this project, a brief introduction to Codex history and the role of FAO/WHO in formulating of codex has been mentioned the importance of codex and its regulations.

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Food allergens have been described and also compared to the regulation regarding food allergens labelling in different countries. Food allergens which are now regarded as one of the food hazards have gained importance due to the increase in food allergy incidences in many countries especially in US, Canada, Europe, Australia, New Zealand, UK, and Japan where the regulations regarding food allergens are very strict. In developing countries like India and China, the regulations regarding food allergens labelling are not as well defined as developed countries, but since these developing countries thrive on trading business as one of the means of earning, allergen labelling has to one aspect that has to be taken into considerations among other aspects of foods safety. Food allergen management in industries which is a very important topic to be considered, also manufactures are recognizing this food hazard and using methods like precautionary labelling as means of cautioning the hypersensitive consumers. Finally, the project report talks about what improvement should be considered in labelling standards stated by Codex.

2. Food Allergens

2.1 Food Allergens: What Are They?

Food allergy is an adverse and undesirable reaction caused by immune system, this kind of reaction is also termed as hypersensitivity reaction which is mediated by immunoglobulin E (IgE); and triggered by certain agents called allergens or exogenous macromolecules mostly proteins which cause the symptoms to appear very rapidly. The allergen is designated according to the Latin name of the species from where it originates, allergen is written by including the first three letters of the genus followed by the first letter of the species finishing with an Arabic number, e.g., Glym1 is an allergen from soya called *Glycine max* [1].

Food allergy is different from food intolerance (non-immune-mediated reactions) which may cause the symptoms to appear after few days. Food intolerance or non-allergic food hypersensitivity

reactions or pseudo-allergy are triggered by certain food components, for example, lactose, amines and histamine [1]. As compared to food intolerance, food allergy can cause anaphylaxis, which can be defined as a severe, whole-body allergic reaction to allergens [1, 3] and requires much stricter avoidance of allergy causing agents (allergens or haptens).

Food allergy can also be distinguished from allergy-like food poisoning in which the reaction occurs as a result of ingestion of histamine from foodstuffs like spoiled tuna, mackerel (species of fish) etc., while food allergy causes release of histamine from the cells, which act as a primary mediator for the allergic reactions [1, 3].

2.2 Brief History

Food allergy is not a hazard of the 21st century; it was a serious issue even before Christian era. According to Hippocrates (460 BC-370 BC) who is also known as the father of medicine “for cheese does not prove equally injurious to all men, for there are some who can take it to satiety, without being hurt by it in the least, but, on the contrary, it is wonderful what strength it imparts to those it agrees with; but there are some who do not bear it well, their constitutions are different, they differ in this respect, that what in their body is incompatible with cheese, is roused and put in commotion by such a thing; and those in whose bodies such a humor happens to prevail in greater quantity and intensity, are likely to suffer more from it. But if the thing had been pernicious to the whole nature of man, it would have hurt all. This statement by Hippocrates states that food can be the cause of many ailments in human beings [4].

In 1906, one of physician Dr. Clemens von Pirquet suggested the use of the word “allergy” to describe sudden reaction to food and other substances [4].

2.3 Food Allergens: Molecular Basis

Food allergens are antigens that elicit allergic reactions; these antigens composing of particles in the size range of 20-40 kDa [5] have glycoprotein which is

resistant to digestion. These antigens are recognized by the immune system, causing to develop Type 1 or Type IV allergy in which either IgE are produced, or specific T-cell antigen receptor (TCR) are produced respectively. The molecules or proteins that are responsible for IgE mediated allergic reactions, share these characteristics, they have molecular weight greater than 3 kDa and can elicit an antibody response, they are stable against any kind of degradation against enzymes and chemicals like the environment of a stomach, they are also stable against any kind of heat treatment during processing, and they have both B-cell and T-cell epitopes [6].

Food allergies can be divided into two types acute and immediate and delayed. Immediate food allergies are easily recognized and are obvious, if a person suffering from peanut allergy comes in contact with the allergen, the patient can himself recognize it. Acute allergies are less prevalent and may cause death. Delayed food allergies are more prevalent as compared to immediate type allergies and may cause indistinguishable symptoms such as chronic headaches or indigestion [7].

Food allergies may cause anaphylaxis, which can be potentially fatal instantaneous oversensitive reaction [5]. It has been estimated over 10 years of study that sudden death due to the food anaphylaxis is 0.06 deaths in 1,000,000 (children aged 0-15 per year). Milk allergy causes approximately of 50% of deaths, and nut allergy causes severe anaphylactic reactions. It has been estimated among children that one in 800,000 children die per year due to food allergy [5].

Food allergies may lead to adverse reactions such as it can cause toxic reactions to components such as histamine, IgE mediated allergic reactions can elicit an response within minutes or hours after ingestion of an allergic food, and once a susceptible person becomes sensitized to a particular allergen after frequent encounters, the IgE bounded to the surface of histamine packed cells interacts with the allergen, this triggers release of histamine and other inflammatory mediators. It is these mediators that cause the symptoms authors know as an allergic reaction (Fig. 1) [6]. The amount of

exposure to an ingested, allergenic food protein needed to elicit a hypersensitive reaction studied to be in the microgram to low milligram range [8].

The universal symptoms of food allergy includes the following symptoms which affect the respiratory system, circulatory system, nervous system, digestive system and circulatory and respiratory system [9].

Respiratory system: symptoms include asthma, difficulty breathing, earache, fainting, Hoarseness, itching, paleness.

Circulatory system: chills, dizziness, fainting, heart attack, irregular heartbeat and weak pulse.

Nervous system: dizziness, fatigue, hyperactivity, and migraines.

Digestive system: abdominal pain, belching, bloating, constipation, diarrhoea, difficulty swallowing, indigestion, itchy mouth, nausea, vomiting.

Circulatory and respiratory system: symptoms of anaphylaxis: dizziness, fainting, gastrointestinal symptom, heart arrhythmias, hives and angioedema, low blood pressure, respiratory symptoms, tunnel vision. True food allergies affect the skin first, for example, if a person comes in contact with a food allergen he/she is susceptible to say seafood, he/she may first develop

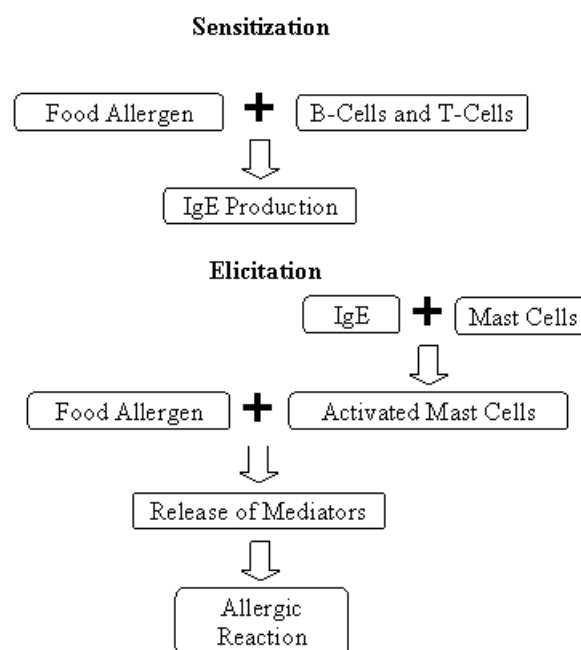


Fig. 1 Mechanism of allergic reactions [10].

hives which occur when an allergen triggers histamine release and these histamines let fluid to leak out from blood vessels underneath the skin which results in hives. These hives are extremely itchy, and they seem like raised white areas surrounded by reddened are on the skin. People allergic to soy and wheat may develop eczema like symptoms, 40% of children who have eczema also have food allergy [9].

2.4 Introduction to Specific Allergens

According to Codex Alimentarius of General Standards for the Labelling of Pre-packaged Foods (section 4.2.1.4), the following foods and ingredients are known to cause hypersensitivity and shall always be declared, this list of eight major allergens was adopted in 1999 at its 23rd Session Codex Alimentarius commission [8], these products are also described in Table 1.

(1) Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;

(2) Crustacean and products;

(3) Eggs and egg products;

(4) Fish and fish products;

(5) Peanuts, soybeans and products of these;

(6) Milk and milk products (lactose included);

(7) Tree nuts and nut products;

(8) Sulphite in concentrations of 10 mg/kg or more.

Some fruits and vegetables are associated with oral allergy syndrome (OAS), but these are not included in the list of Codex [8] for ex, some people in Japan have found to be allergic to kiwi fruit and banana [11]. Food additives such as azo-colours preservatives benzoic acid/benzoates, and the antioxidants

butylhydroxyanisol (BHA) and butylhydroxytoluene (BHT) are also known to cause allergies [12].

In developing countries like India besides big 8, sesame chickpeas, rice fried foods and non-vegetarian foods have also recognized as allergens [13].

Different countries have different allergen labelling requirements. In Canada besides the major 8 allergens, sesame seeds and molluscs also need declaration on labels which is same for South Africa. In Europe, besides top 8 molluscs, sesame seeds, celery, lupin and mustard also need declaration. In Japan besides big 8, molluscs also need to be declared [6].

2.5 Different Types of Food Allergens

Food allergy can be caused by many kinds of food stuff and elicits a response that can be life threatening to hypersensitive individuals.

People in different countries are susceptible to food stuff that depends on their consumption patterns and dietary habits during childhood.

2.6 Food Derived from Biotechnology and Food Allergy

Novel foods may also cause allergy, examples are genetic modification of the food or production of the food by using novel techniques like recombinant DNA technology, or a food may be new to some country, i.e., exported from another country new cases of food allergy. The introduction of novel proteins into the food chain and the human diet like genetically modified animals, plants and microorganisms can cause allergic reactions in two ways either cross-reactivity with another allergen to which patients are susceptible or by acting as a completely new allergen (de novo sensitisation) [18]. In

Table 1 Specific food allergens.

Food	Reaction	Prevalence	Dose response
Tree nut-Almond, beech nut, Brazil nut, Butternut, Cashew, Chestnut (Chinese, American, European, Seguin), Chiquapin, Coconut, Filbert/hazelnut, Ginko nut, Walnut, Hickory nut, Lichee nut, Macadamia nut/Bush nut, Pecan Pine nut/Pinon nut, Pili nut, Pistachio, Sheanut [14].	Even very small amount of nuts leads to anaphylactic shock [14].	In US, 0.4%-0.6% of the population. In France, Germany, Israel, Sweden, and the United Kingdom vary between 0.03% and 8.5% [15].	Not known

(Table 1 continued)

Food	Reaction	Prevalence	Dose response
Fish-Anchovy, basa, bass, bluefish, bream, carp, catfish (channel cat, mudcat), char, chub, cisco, cod, eel, halibut, herring, mackerel, mahi-mahi, marlin, monkfish (angler fish, lotte), orange roughy, perch, pickerel (dore, walleye), pike, plaice, pompano, rockfish, salmon, sardine, shark, smelt, snapper, sole, and sturgeon etc [16].	Fish allergy (major allergen protein parvalbumin) may cause an anaphylaxis attack even in minute quantities. People with fish allergy may also suffer from frog allergy. The symptoms of fish allergy include itching in mouth and may also cause oral allergy syndrome.	In the United States, 0.2% of children and 0.55% of adults suffer from fish allergy. Among adults, 0.6% of women and 0.2% of men suffer from fish allergy.	Cod as low as 5mg [1, 3]
Shellfish and Crustacean-Crustaceans like Crab, crayfish (crawfish, écrevisse), lobster (langouste, langoustine, coral, tomalley), prawns, shrimp (crevette) and shellfish like, clam, cockle, conch, limpets, mussels, octopus, oysters, quahaugs, scallops, land and sea snails, squid [1].	2% of adults in United states suffer from shellfish allergy .It is also the most common cause of exercise -induced anaphylaxis.	In US, 0.5% of children and 2.5% of adults suffer from crustacean shellfish allergy. Among adults 2.6% of women and 1.5% of men suffer from crustacean shellfish allergy [1].	Even inhalation of shellfish allergens may elicit an allergic reaction in some people [1, 3].
Milk (major allergens recognised in milk are casein, beta-lacto globulin alpha-lactalbumin and alpha-lactoglobulin)	Some Infants may have acute allergy to milk immediately after weaning, it may be temporary up to 3-4 years. But another slow form of milk allergy affects older children.	In Canada, 1-2% of population and 2-8% of children suffer from milk [9].	0.6 mg to 180 mg of milk can elicit a response [1, 3].
Eggs	People allergic to milk are often allergic to eggs mostly egg white (60% of egg) also Symptoms include itching of the mouth and pharynx; eczema, pruritis and dermatitis, and urticaria; nausea and vomiting; rhinoconjunctivitis and in very rare cases anaphylaxis [1, 3].	Egg allergy is one of the commonest allergies found in children, with a prevalence of about 2%. Hen's eggs are the most common allergen in Japan. In a Norwegian cohort, the occurrence of hen's egg allergy was estimated to be 1.6% [15].	1 mg of liquid egg can elicit an response [1, 3].
Legumes-soy beans (glycine max.), peas, peanuts (25% of protein)	Protein residues present in starch and fibre products from these legumes may be enough to manifest symptoms of hypersensitivity.	In US, 0.06%-5.9% of population suffer from peanut allergy [17]. According to some studies, prevalence of soy allergy is between 0.3% and 1.0%, with a slightly higher prevalence in children than in adults [1, 3].	100-50 mg [1, 3]
Cereals-Wheat would include grains such as: Commonwheat (<i>Triticum aestivum</i> L.), Durum wheat (<i>Triticum durum</i> Desf.), club wheat (<i>Triticum compactum</i> Host.), spelt (<i>Triticum spelta</i> L.), semolina (<i>Triticum durum</i> Desf.), Einkorn (<i>Triticum monococcum</i> L. subsp. <i>monococcum</i>), emmer (<i>Triticum turgidum</i> L. subsp. <i>dicoccon</i> (Schrank) Thell.), kamut (<i>Triticum polonicum</i> L.), and triticale (<i>Triticosecales</i> sp. Wittm.). Also rye, barley and oats.	The majority of allergic reactions to wheat are caused by the albumin and globulin fractions. Consumption of wheat before exercising may lead to wheat-dependent exercise-induced anaphylaxis in adults [1, 3].	More common in children A study in Australia suggested that there was a prevalence of about 0.25% amongst young adults [1, 3].	In Germany, doses of between 4 mg and 3.5 g of wheat flour, are required to induce symptoms [1, 3].
Sulfites compounds containing the sulfite ion (sulfur and oxygen), most often in combination with sodium (sodium sulfite) or potassium (potassium sulfite).	People allergic to some food additives can appear even though they are not allergic to other substances, like sulphite as low as 10 ppm can give allergic symptoms in people suffering from asthma. People who suffer from asthma ,they are more prone to anaphylaxis and may lead to respiratory symptoms.	A Danish study reports a prevalence of 1%-2% among school children. Prevalence of sulfite. Allergy in steroid-dependent asthmatic children is estimated to be between 20% and 66%, while prevalence in steroid-dependent asthmatic adults is estimated between 3.9 and 4.5% [1, 3].	10 mg/kg of food [1, 3]

1996, the issue of allergenicity was addressed by Joint FAO/WHO Consultation on Biotechnology and Food Safety, and following criteria were set for allergenicity in novel (GM foods), these are:

- (1) There should be no gene transfer from common allergenic foods otherwise specified;
- (2) Appropriate measures should be employed by organizations if any food containing new proteins show allergenicity;
- (3) The identification of possible food allergens and their characteristics should be defined.

Some of the assessment guidelines (decision-tree approach) are set by Codex in 2003 for these GM allergic food stuff, these are assessment of source of protein, amino acid sequence homology, pepsin resistance test, and specific serum screening test.

2.7 Food Allergies on the Rise

Naturally occurring proteins or food allergens are responsible for food allergies and it is increasing around the world. About 10% of the population suffers from some form of the food hypersensitivity around the world. According to CDC in US, 12 million people live with food allergies [9]. According to Swedish official report food hypersensitivity occurs in about 20% of children up to three years old, 8% among six-year olds, about 15% among young adults, and is most likely just as frequent in older people[19]. In US in the year 2007, three million children under the age of 18 were reported to have a food or digestive allergy. The prevalence of food allergy among children under the age of 18 increased 18% from 1997 to 2007. 2.3% of population in America is allergic to seafood. Also, it is estimated that the number of cases of anaphylaxis from foods in the US increased from 21,000 per year in 1999 to 51,000 per year in 2008. In countries like Australia and Newzealand, more than 8% of children and 2% of adults suffer from food allergies. Children may outgrow some allergies, such as milk and egg more likely than peanut and nut by the age of 5-7 years. In UK, since 1990 food hypersensitivity reaction

increased hospital admissions by 5,000% [9]. In Japan, the top three most common cause of food allergy in Japan are hen's eggs about 30.3% cases are due to hen's eggs followed by 15.9% cases due to milk as indicated by studies done in Japan [11]. In China, food allergy reportedly affects 3.4-5.0% of residents in Beijing. In Indonesia, adverse reactions to chicken (13.5%), cashewnut (5%), banana (11%) and pineapple (23.5%) were reported by a study done on 600 children [20]. Class 1 level (reasonable probability that the use of, or exposure to an allergen will cause serious health), food recalls (like microbiological, chemical, extraneous, and other) were reported from 1997-2001. In Canada, the majority of recalls were allergen related and about 75.7% recalls in Canada were reported due to food allergen in the year 2000-2001 [21].

3. Introduction to Food Safety

3.1 Food Safety: Brief Information

Food safety is a major issue in both developed and developing countries and due to the escalation of trading business between these countries; emergence of new pathogens as well as contamination has become an inevitable thing. In developing countries, the issue of food safety is more serious as they are in verge of their expansion or rapidly growing and about half of the agricultural exports comes from these countries, poor food safety management leads to not only financial losses in the local market but in international market as well which affects the farmers in rural areas; poor food safety also contributes to many diseases in these countries. Effective food safety management system such as implementation of HACCP and GMP is required in developing for controlling not only food borne pathogens but also food allergens.

3.2 Food Safety in Developing Countries

Food safety in developing countries has become a paramount issue nowadays with the rising incidence of Food-borne diseases, as well as food allergens. In

developing countries, trading is one source of income, especially export of fresh foods and other novel ingredients, but this is hindered due to various food hazards encountered in developing countries. The challenges faced in terms of regulation and standards by the developing countries in the international market are very different from the domestic market. Proper investment is needed in reduction of food hazards, and knowledge of good manufacturing practises is very important for the management of food safety as well as safe trading of food items from developing countries. Also, abolition of trade barriers to fresh food product exports will lead to the economical development of the rural areas who are the producers of fresh foods in these countries [22]. Developing countries should meet with the agreement by international agencies such as WTO, as well as SPS and TBT agreements. Developing countries need to also participate in international organizations like Codex for the setting of internationally recognized standards and strengthening their food management system [23].

3.3 Food Safety Hazards (Allergens)

Food allergy is a growing food hazard and both developed and developing countries have to address this issue. Food allergens can be considered as food hazards as they pose serious health implications on the hyper-sensitive individuals. Food allergens have also negative socio-economic impact, firstly it affects the quality of life of individuals, and secondly government has to bear both medical and non-medical expenses for the prevention and treatments of food allergies. According to European white paper on allergies in EC the total costs of the major allergic diseases (including allergic rhinitis, allergic asthma, atopic dermatitis, contact dermatitis and urticaria) are estimated at 10 billion.

Management of food allergens especially eight major serious allergens (MSAs), is difficult since there is incomplete scientific understanding on them, also with the trading of novel and exotic foods this issue becomes

more complex. More stringent regulations are required as well as more study on prevalence and emergence of allergence is required to know the extent of food allergency in one country. In countries like Canada, US, Europe and Japan, studies have been done to know the complexity of this issue and appropriate measures have been taken to keep this problem at bay [24].

3.4 What is Codex Alimentarius: Historical Perspective

Governing authorities in historical times were also concerned with codifying of rules for the safety of food, some evidences are the “Assyrian tablets that described the method of determining the correct weights and measures of food grains”, “Egyptian scrolls prescribed the labelling to be applied to certain foods”, beer and wines were inspected in Athens for purity, Romans used to keep a well controlled food safety system, food quality control measures were mentioned by Kautilya (an Indian statesman) in the year 300 [25]. During the middle ages, some of the countries in Europe passed laws for the safety and quality of food stuff like eggs, sausages, bread, wine and bread [17].

The middle of 19th century was the era when the first food law was adopted, food chemistry discipline was recognized and it was adopted as a suitable method to check the purity of food stuff and to recognize any adulterated products. Since every country was formulating their own food laws, this was creating a trade barrier which leads to the formation of trade associations in the early 1900s like IDF founded in 1903 which pressurized the government in different countries to develop food standards for the safety of food and whose quality is defined and apply to all countries.

FAO and WHO were founded in the year 1945 and 1948 respectively. At the same time, with the advent of progress of food science and technology, a lot of information about food safety was getting generated both true and untrue, consumers nationally and internationally were now more aware about the visible underweight contents, size variations, misleading labelling and poor quality and invisible health hazards

that could not be seen, smelled or tasted, such as micro-organisms, pesticide residues, environmental contaminants and food additives contents of food. These well-informed consumers pressurized the government to adopt regulations and methods to control and safeguard food both from poor quality and food hazards. This resulted in different countries taking food safety issue seriously. In 1949, Argentina proposed a regional Latin American food code, known as Código Latino americano de Alimentos, Austria between 1954-1958 also followed the creation of regional food code, the Codex Alimentarius Europaeus [17].

In the year between 1960 and 1961 in the regional conference of FAO, Codex was founded. Then followed a conference between FAO and WHO, the United Nations Economic Commission for Europe (UNECE), the Organisation for Economic Co-operation and Development (OECD) and the Council of the Codex Alimentarius Europaeus for the establishment of an international food standards programme, and in May 1963, at the 16th World Health Assembly approved the establishment of the Joint FAO/WHO Food Standards Programme and adopted the statutes of the Codex Alimentarius Commission.

Codex was a revised and well documented of guidelines related to food that aims to protect the consumer's health, of ensuring quality and of reducing trade barriers. Codex is a collection of standards, codes of practice, guidelines and other recommendations which deal with the requirements of a specific food or groups of food like packed or frozen foods, allergic foods etc., it also deals with how should food industries operate and manage their production processes for the protection and safety of food supplied to the customers. Codex standards covenant with the various characteristics related to product that has been regulated by the government [17].

3.5 Understanding Codex

Codex can be defined as the forum for developing standards, and where different countries can exchange

their ideas and views on food safety and quality. It provides its member countries with the following information:

- Development in food safety and quality at international level;
- Any new technological development in food safety and quality area;
- Introduction of new products in marketplace;
- Measures undertaken in the management of food safety and quality concern.

The difference between Codex Alimentarius and Codex Alimentarius Commission are that the first one is a set of guidelines and standards regarding food safety and the second one is the main body that develops these guidelines and standards [23].

The Codex Alimentarius Commission consists of four organizational elements, these are: the commission, the executive committee, the codex secretariat, and the codex subsidiary bodies. The Codex subsidiary body comprises of general subject committee or horizontal; committees, commodity committee or the vertical committee; FAO/WHO coordinating committee and ad hoc intergovernmental task force. The codex commission by 2005 has a total of 171 member countries and one member organization [23].

Codex alimentarius commission has the following duties:

- Protecting the consumer's health;
- Ensuring fair trade practises;
- Harmonizing all food standards work;
- Preparing of draft standards;
- Finalizing and publicizing these standards in Codex alimentarius;
- Revise the standards published.

3.6 Significance of Codex

Food is a primary or basic need of every human being. Food has undergone significant changes, from farm to table it goes through many processes thus safety of food is very important and government as

well as the vigilant customers are becoming more and more aware of the safety as well as its quality. Food hazards leads to consequences also, for instance in US there were 103 food recalls, out of which, 48 were due to undeclared food allergen ingredients as reported by the federal food safety agency [26]. Food recalls leads to financial loss of the company as well as loss of integrity in the market. In developing countries, trading of food is a major source of capital, poor quality of food can damage trade and tourism as well can lead to lawsuits and in some cases unemployment. National as well as international trade can be hampered due to poor quality of food.

FAO and WHO is playing a significant role in strengthening and implementation of Codex standards to build up national as well as international food control. FAO and WHO assist developing countries in adopting and implementing the food law by providing them with financial as well as methodological support, which is further improved by support from developed countries and international funding institutions. Through the introduction of Codex standards, the codex alimentarius is playing a crucial role in putting food as an important entity which the government and the industries should consider both in developed and in developing countries. Codex has been universally accepted as the most important set of guidelines and ensures consumers protection not only from various Food-borne diseases but also from recent growing incidence of food allergies among hypersensitive individuals. Technical assistance is also being provided to developing countries by FAO/WHO like; reinforcement of food control systems in developing countries, and providing assistance to the food control agencies, along with appropriate training for the appropriate function of the agencies. The FAO/WHO is trying to increase awareness of the codex and its activities that pertain to the needs of the industries that might be helpful in production and distribution of safe food throughout the country, manuals are also published that states information regarding food

inspection and quality and safety assurance guidelines in food industries particularly with respect to the application of the HACCP system. The easy access of information about food standards makes it convenient for food industries to retrieve any information.

In 2003, a trust fund was launched by FAO/WHO to help increase participation of developing countries in codex work and improve the safety and quality of food production. The international organizations associated with codex are making efforts in combining the information on food standards which are reliable and not doubtful or incoherent.

3.7 Codex and Food Safety

The codex comprises of standards for principle foods including processed, semi-processed or raw. The codex Alimentarius has provisions for food additives, contaminants, food hygiene, inspection and certification, labelling and presentation, methods of analysing and processing, pesticides residues, veterinary drug residues. A provision for food allergy was added in the codex in the year 1999.

3.8 Challenges Faced in Developing Countries

Developing countries have to follow certain norms and condition while trading of food commodities, this quality and safety norms are set up by the WTO in the SPS and TBT agreements. The codex alimentarius covers all the standards as compiled by the WTO regarding food safety issues. Some countries like India have food standards different from the codex standards, Codex standards are more wide-ranging, and have provisions for quality, hygiene, food additives, labelling and method of analysis and sampling. Besides these provisions, the provision for food allergens has also been included. The standards for food safety and quality in developing countries like India are different on basis of food additives and contaminants, and the standards for food allergen labelling are also not very strict.

In India, standards for food quality are laid down in prevention of food adulteration and the emphasis of

this act is on food adulteration and there is no provision for food additives, contaminants and labelling, hygiene relating to handling and processing of food and methods of sampling and analysis. The harmonization of PFA and codex standards is a difficult task because developing countries do not have active participation in the codex alimentarius commission, also the commission is dominated by developed countries and make standards that suit their technological development and do not pay attention to the needs of the developing countries that lack technological advancement [27]. Factors like difference in culture, production practises, climatic condition also affect the food safety risks in countries in Asia pacific region, also the food systems, controls and policies are not yet fully developed. To strengthen the food control system in Asia pacific regions, Codex Alimentarius Commission has made available funds, which aims at creating an efficient food safety system that will enable Asian countries to meet international standards and improve their technological skills [28].

3.9 Codex Standards and WTO

The codex or the food code has an important role in international trade. Codex provides globally with uniform standards that can be implemented by different countries to protect the consumers against food hazards such as food allergens, also with the increasing global economy the import export of food items [27].

Food allergens are becoming major problem in both developed and developing countries. Recently, in the first quarter of 2011, according to the Federal food safety agency statistics, food items such as frozen spring rolls and rice balls exported by China to Australia were recalled due to no marking of peanut. These incidences happened because of the poor labelling of food items. There is need of strict labelling guidelines of allergens when food items have to be exported between different countries. International food standards can make food trade safer and securer. Substantial government as well as private resources and

expertise are spent on the Codex standards to ensure safe transport of food and safeguard public health [29]. In January 1995, the WTO was created, at the same time, the two agreements on international food trade; they were the Sanitary and Phytosanitary measures SPS agreement and the technical barrier to trade TBT agreement also were established. The SPS recognizes guidelines and recommendations associated with the Codex alimentarius commission. The SPS covers measures applied for the protection of human, animal and plant health. Also, WTO members have to base their food safety measures on codex standards [23].

4 Food Allergens Management

4.1 Management of Food Allergens in Food Industries

Food allergens management in food industries is a major challenge for the food producers, as the food has to be monitored for allergens at different stages of production, also the various equipment used for the production of different food stuff has to be monitored for any kind of contamination by allergens. Accurate labelling is one of the risk management strategies employed by the food industries to inform the consumers about possible allergen present in food.

Precautionary or advisory labelling is one of the risk management procedures employed by the food industries to advise the consumers, that the food stuff may contain or be potential to contain one or more allergens and the allergen has not been purposely added to the food item. Various possible ways of unintended inclusion of allergens are: application of the same instruments for the production of food stuff having different allergens (cross-contact). Cross-contact can take place when many foods are produced on the same processing line or through the use of shared storage and transportation equipment. According to good manufacturing practices, voluntarily use of precautionary labelling is done by food manufacturers to alert the consumers about unintentional presence of allergen in food. Precautionary statements such as “may contain” or “may contain traces of” are often

used [1]. Thus kind of additional information provided by the manufacturers to protect them from any kind of legal action in future, if a susceptible person suffers from any kind of reaction after eating a food item, this kind of labelling is just an additional information for the non-food-allergic consumers but very useful piece of information for the allergic consumers. Canadian food regulators in the early 1990s selected precautionary labelling as a method of risk management for food allergens. Health Canada defines a “food allergen precautionary statement” as “a declaration on the label of a pre-packaged food of the possible inadvertent presence of an allergen in the food.” Examples of statements of precautionary labelling in Canada are as follows:

“May contain X”, “may be present: X” is used to indicate the presence of possible allergens in food.

“Manufactured in the same facility as products containing X”, “packaged in the same facility as products containing X”, if a food item processed or packaged in same facility an allergen has been processed or packaged.

This kind of statement shall not be used when an allergen or allergen containing ingredient is deliberately added to a food [30].

5 Codex Guidelines on Food Allergens

5.1 Codex Alimentarius Section on Hypersensitivity

Hypersensitivity is a problem that is increasing in many parts of world; as a result food labelling has become very important of the allergy causing products. Throughout the world in many countries, the Codex General Labelling Standard provides the basis for national food labelling regulations for allergy causing food. With the growing of trading activities also new products are being introduced to one country from another country, this adds to the importance of the labelling regulations which should be uniform, sufficiently precise throughout and the labelling designations used should be well-known, unmistakable, and not confuse the consumers [31].

5.2 Labelling of Food Allergens

According to the report of the 22 session of the codex committee on food labelling published in 1993, the main rule for the declaration of ingredients in the codex general standard on labelling is that all ingredients shall be listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food.

5.3 25% to 5% Rule

The Codex general standards on labelling had few provisions that did not pertained to consumer needs which was rectified afterwards, these provisions are as follows: [31]

25% rule: according to the Codex General Standard on Labelling, where an ingredient is itself, the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients provided that it is immediately accompanied by a list in brackets of its ingredients in descending order of proportion (m/m). Where a compound ingredient for which a name has been established in a Codex standard or in national legislation constitutes less than 25% of the food, the ingredients other than food additives which serve a technological function in the finished product need not be declared.

According to the stipulation, if an allergen is present in small amounts in a food item as an ingredient, it has to be declared; but if the same allergen is present in much larger amounts in another product as a component of compound ingredient (less than 25% of food), it is not declared. This created difficulties to allergic individuals who have to avoid a number of commonly eaten ingredients, also as many non-traditional ingredients are being imported, there has been increased in the introduction of novel foods, it has become essential that labelling should be detailed and precise, for example fat substitutes made from egg are shown to induce symptoms in people allergic to eggs. It is necessary to ingredients like these are

specified on the label. The only solution to this kind of situation is lowering the limit for specifications; this lower limit could be set at 5%. Lowering the limit will null the requirement of declaring the components of a compound ingredient in many cases, but not for potent allergens.

Class names: according to the General Standard of labeling, some of certain ingredients can be declared using class name instead of specific name, for example: peanut oil can cause allergic reactions in some people, but it did not need to be declared specifically, but instead it is declared by its class name “vegetable oil”. This leads to confusion among consumers. The only solution to this problem is declaration of such ingredients by their specific names.

Carried-over food additives and processing aids: according to the 25% rule, “food additives in the compound ingredient which have a technological function in the finished product shall be declared even though the remaining ingredients in the compound ingredient need not to be declared”. This is also provided for in section 4.2.3 of the General Standard, which states:

4.2.3.1 A food additive carried over into a food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used shall be included in the list of ingredients.

4.2.3.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, which are exempted from declaration in the list of ingredients.

But some ingredients such as sulphites as low as 10 mg/kg showed hypersensitivity reactions in susceptible consumers. So with the description of this example even the labelling of food additives that are carried over with raw materials and compound ingredients should be mandatory regardless of whether or not they have technological effect because compounds like sulphites even in low prove may prove fatal to the

asthma patients.

5.4 Quality Standards

To maintain quality standards in food and detection of hidden allergens, a number of methods have been adopted by food industries, these methods are ELISA, PCR, Biosensors, Mass spectrometry. PCR can be applied for the detection of genes encoding for allergenic food proteins, RT-PCR can detect peanut gene Ara h2 in cookies, chocolate bars with a LOD of 10 mg/kg. Besides food labelling industries are employing these methods to maintain the quality standards of food and elimination of allergens which in low amounts can cause serious problems [32].

5.5 Food Allergens Guidelines in Developed Countries

Food labelling for allergens has gained importance in recent years. In Europe, the food labelling regulation for allergens was implemented in the year 2005, according to which all pre-packed food and drink items met the labelling criteria, also the 25% rule was abolished and instead list of all ingredients that constituted the product even less than 25% had to be listed by the manufacturers, in addition the additives used during processing, the solvent and media for additives and flavours also had to be listed in the label [33].

Twelve allergenic foods that must be labelled in Europe are (cereals containing gluten, crustaceans, fish, egg, peanuts, soybeans, milk, tree nuts, celery, mustard, sesame, sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/litre, expressed as sulfur dioxide. These ingredients should be labelled, if they are used in food production. EFSA European Food Safety Authority has the authority to add more allergic ingredients to the list since different people have different tolerance level to food allergens. EFSA can grant temporary labelling exemption to the processed food items in which the allergenic risks have been removed due to some kind of processing.

In England, Scotland, Wales and Northern Ireland

the Food Labelling (Amendment) came into force on the November 26, 2004. According to this amendment, all allergens and the ingredients derived from allergens used in food stuff should be indicated with their source. Under UK regulations, the allergen information is provided by putting it in box “Allergen Information” but it’s not mandatory by law and voluntary can be done by manufacturers.

Under US Legislation according to Food Allergen Labelling and Consumer Protection Act 2004, the food manufacturers should identify the eight common food allergens, these are wheat, eggs, milk, fish, crustacean shellfish, peanuts, nuts and soya beans and the allergens if used in spices, flavours or colours or as additives must be stated, too [34].

In Canada, it has been estimated that 1%-2% of the adults and 5%-8% of children are allergic to one or more particular foods. According to some test, it takes about 1-2 mg or may be less of allergic food to elicit allergic reactions in sensitive individuals. Food stuff like peanuts, tree nuts, soy, milk, eggs, fish, crustacean and shellfish, sesame seeds, sulphites, and wheat have been recognized by both Health Canada and the Canadian Food Inspection Agency (CFIA) as potent allergens, these food are responsible for 90% of adverse food reactions among the Canadian population. CFIA in collaboration with Codex commission develops various standards and guidelines for food and implements them. For risk management of allergens, Health Canada has developed a Policy on Food Allergens for Compliance Purposes which can be used by CFIA to recall any product which has not been properly labelled. Some criteria set in this policy document are:

Presence of peanut should not be greater than or equal to 1 ppm and if not declared it can be recalled. The amount of tree nuts (named), sesame seeds, soy, cow’s milk, eggs, fish, crustaceans and shellfish, wheat and sulphites added as ingredients/additives to a food should not exceed 10 ppm and , when peanut protein is detected in a food at levels greater or equal to 10 ppm

and is not declared on the label, Health Canada would support a recall and public alert [21].

In Japan, according to Ministry of health labour and welfare labelling of egg, milk, wheat, buckwheat, and peanut is mandatory along with shrimp, prawn and crab even if they are carried over or used as processing aids. Since allergies to fruits such as kiwi, banana is increasing in Japan; MHLW is also reviewing this issue. Total 18 sub specific ingredients are recommended by MHLW for labelling, these are: abalone, squid, salmon roe, orange, kiwifruit, beef, walnut, salmon, mackerel, soybean, chicken, banana, pork, matsutake mushroom, peach, yam, apple, and gelatine. May contain (name of allergenic ingredients) type labelling is prohibited in Japan. High-grade food ingredients such as abalone, salmon roe, and mushroom mixed in very small quantities, for their declaration such as “contains xxx extract” is required. Food additives are declared by specifying the “name of the substance (derived from)” [11].

In Hong Kong, the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2004 was enacted on July 9, 2004. This act had aspects like good manufacturing for the control of allergens in industries, and proper food labelling by manufacturers which compliance with food Labelling regulations provided by Codex allergens can be declared by following ways: [35].

“May contain traces of (NAME OF ALLERGEN)”;

“Contains traces of (NAME OF ALLERGEN)”;

“Produced in a factory where (NAME of ALLERGEN)” is also handled.

5.6 FDA Regulations on Food Allergens

The Original Food and Drug Act of 1906, had no provision for declaration or requirement of disclosing of any allergic ingredients used in food stuff, this unregulated system was causing numerous health problems in US. As a result Congress passed the FD & C Act in 1938, and according to this act “it was required to label all food stuff made-up from two or

more ingredients and declare each ingredient by its common or usual name". The act came to power after an incident of legally marketed toxic killed 107 people. This act authorized FDA to issue standards for food, as well as permitted FDA to conduct factory inspections. This act also provided information to food allergic consumers but in some cases like unfamiliar names of some allergens, the consumers were not able to recognize the food allergens and the ingredients derived from these allergens, thus the enactment of the Food Allergen Labelling and Consumer Protection Act of 2004 came to power (Fig. 2). According to this act milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (crab, lobster, or shrimp), and tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans or any ingredient derived from these allergens are major food allergens (responsible for 90% of food allergies) and should be declared especially in case of tree nuts, fish and crustacean shellfish. This law covers all packaged food items manufactured domestically or imported [10].

FALCPA requires the food manufacturers to label food products made from the ingredients derived from major food allergens, in two ways:

By including the name of food source in parenthesis followed by the usual name of major food allergen in list of ingredients (a), or by stating the name of the major food allergen after the word "contains" (b).

Nutrition Facts	Nutrition Facts
Ingredients : whey (milk), lecithin (soy)	Ingredients: whey ,lecithin
	Contains : whey and soy
(a)	(b)

Fig. 2 Labelling of allergens [10].

In 2001, priority was given to food allergens management in industries by FDA because these agents can be life-threatening to the perceptive individuals and as there is no cure for food allergy, avoidance is the only alternative. CFSAN the Center for Food Safety and Applied Nutrition is one of FDA's product-oriented centers, which provides guidance to industries on how to manage allergens through proper labelling and manufacturing practises. According to Federal Food, Drug, and Cosmetic Act under 21 Code of Federal Regulations (CFR) 102.22 the food source identification for protein hydrolysates e.g., "hydrolyzed wheat gluten" and "hydrolyzed soy protein" should be declared, failure to do so in past by some companies has resulted in food recalls. In US in the year 1999, the food recall due to inappropriate allergen labelling was more than 80 per year. In 1996, to limit the growing incidence of food allergy among consumers, and prevent adverse reaction which was due to undeclared of food allergens on the label, a notice was issued by FDA which specified and alerted the manufacturers and trade associations to address the problem of undeclared allergens and declare even if the allergens are present in very low amounts [10].

6. Conclusions

Food allergy is one of the problems that need immediate attention both in developed and developing nations. This kind of atopic disease is widespread and it depends on the dietary, racial and cultural diversity which type of allergy is prevalent in different countries, because of this type of assortment of food allergens around the world makes it a difficult ailment to control unlike microbial diseases. Different countries have different regulations to deal with the issue of food allergens. Codex Alimentarius is one such document of codes which provides with guidelines of how to deal with eight major food allergens. The main advantage of Codex is that it provides with unified set of guidelines to food manufacturers all around the world stating various labelling guidelines such as 5% rule, declaration of class names and carry over additives.

Codex also provides developing countries with financial and technical help to developing countries who face the challenge of technological backwardness and cannot apply these labelling regulations because their allergen labelling regulations are not fully developed. Also, harmonization of labelling regulations is very important regarding food allergens as increase in trading activities between developing and developed countries. Codex is one such international set of guidelines that can help in bringing forth coordination between different countries regarding allergen management.

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